K090496

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5. 510(k) Summary

Submitter's Information:	Cardiac Lead Technologies, LLC 5520 Pembroke Rd. Bethesda, MD 20817
Contact Person:	Claudia Lewis-Eng Phone: (202) 344-4359 Fax: (202) 344-8300
Date Prepared:	August 7, 2009
Proprietary Name:	Qwiklead™ Electrocardiograph Electrode Patch
Common Name:	Electrocardiograph (ECG) Electrodes
Classification Name:	Electrodes, Electrocardiograph
Regulation:	Electrocardiographic electrode, 21 C.F.R. § 870.2360
Regulatory Class:	Class II, Classification Panel 74
Product Code:	DRX
Predicate Devices:	K020003, Telectrode ECG Electrode (Bio Protech Inc.) K073104, Skintact® ECG Electrodes (Leonhard Lang GmbH) K040784, PROTAB ECG Tab Electrode (Bio Protech Inc.)
Description of Device:	The Qwiklead™ Electrocardiograph Electrode Patch configures pre-positioned ECG electrodes affixed to the underside of a single non-sterile, laminated, flexible patch/pad. The patch is a multi-layer construction containing a first layer surface (made of tricot/polyester fabric, polyethylene foam, or polypropylene substrate) including at least one electrode, a second layer (metallic with Ag/AgCl coating) that contains the electrodes, and a third layer (made of biocompatible conductive hydrogel coupling media). The patch is placed on the patient's chest, and no additional electrodes need be placed on the patient's limbs, as is typical for ECG electrodes.

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Intended Use:	The Qwiklead™ Electrocardiograph Electrode Patch is intended for use in general electrocardiographic procedures where ECG monitoring is deemed necessary and is ordered by a physician. Such procedures include, in particular, patient ECG surveillance and ECG diagnosis recording. The Qwiklead™ Electrocardiograph Electrode Patch is intended for single-patient/single application use and is intended to be used on intact (uninjured) skin. The Qwiklead™ Electrocardiograph Electrode Patch is to be used in adults.
Technological Comparison:	The Qwiklead™ Electrocardiograph Electrode Patch has technological characteristics that are substantially equivalent to those of the predicate devices, as determined by testing. The following testing was conducted: AC impedance; DC offset voltage; defibrillation overload recovery; combined offset instability and internal noise; and bias current tolerance. The Qwiklead™ Electrocardiograph Electrode Patch and the predicate devices all meet the specifications as established in ANSI/AAMI EC12:2000.
Basis for Equivalence:	
-Performance testing:	Biocompatibility testing was performed, and the device passed the required skin sensitivity testing criteria. According to the performance data, the Qwiklead™ Electrocardiograph Electrode Patch met specifications as established in ISO 10993-1 for skin contact. The tests included cytotoxicity, sensitization and primary skin irritation tests. The predicate devices (K020003, K073104, K040784) meet the same ISO 10993 specifications. Bench testing demonstrated that the characteristics of the Qwiklead™ Electrocardiograph Electrode Patch are substantially equivalent to those of the predicate devices.
-Labeling:	The labeling of the Qwiklead™ Electrocardiograph Electrode Patch is substantially equivalent to that of the predicate devices.
Conclusions from Testing:	In all material respects, the Qwiklead™ Electrocardiograph Electrode Patch is substantially equivalent to the predicate devices. Testing was performed according to FDA-recognized standards. Test results support the conclusion

that the electrical output is substantially equivalent to the predicate devices, and any differences between the devices do not pose new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cardiac Lead Technologies, Inc.
c/o Ms. Claudia Lewis-Eng, Esq.
Partner
Venable, LLP
575 7th St. NW
Washington, DC 20004

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Re: K090496
Trade/Device Name: Qwiklead™ Electrocardiograph Electrode Patch
Regulatory Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: Class II (Two)
Product Code: DRX
Dated: August 24, 2009
Received: August 25, 2009

Dear Ms. Lewis-Eng:

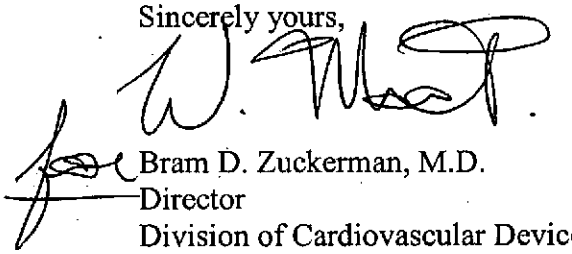
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090496

Device Name: Qwiklead™ Electrocardiograph Electrode Patch

Indications For Use:

The Qwiklead™ Electrocardiograph Electrode Patch is intended for use in general electrocardiographic procedures where ECG monitoring is deemed necessary and is ordered by a physician. Such procedures include, in particular, patient ECG surveillance and ECG diagnosis recording. The Qwiklead™ Electrocardiograph Electrode Patch is intended for single-patient/single application use and is intended to be used on intact (uninjured) skin. The Qwiklead™ Electrocardiograph Electrode Patch is to be used on adults.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090496